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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,108	06/07/2001	Winthrop D. Childers	10008114-1	2356

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/878,108	CHILDERS, WINTHROP D.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,27,28,31-34 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,27,28,31-34 and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 4/16/04 is acknowledged and entered. Claims 29-30 and 35 have been canceled. Claims 1-7, 10, 27-28, and 31 have been amended. Claims 36-43 have been added.

2. Claims 11-26 are canceled by the amendment filed on 9/12/03.

3. Claims 1-10, 27-28, 31-34, and 36-43 are pending.

4. Claims 1-10, 27-28, 31-34, and 36-43 are treated on the merit in this Office Action.

Withdrawn Rejections

5. In view of applicant's cancellation of claim 35, the previous rejection under 35 USC 112, first paragraph (new matter) has been withdrawn.

6. In view of applicant's cancellation of claim 35, the rejection of claims 1, and 31-35 under 35 USC 103(a) as being obvious over Stylli et al. (US Patent 5,985,214) and Pham et al. (US Patent 6,171,780 B1) has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-10 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214).

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38, lines 46-67; col. 39, lines 1-9). The method comprise of dispensing the reagents (pharmaceutical active agent) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18) (referring to claim 1). The electrically sensitive volume displacement unit can dispense a predetermined volume of 500 to 1 picoliter (col. 16, lines 39-44) (referring to claim 4). The wells are arranged in a two dimensional array such as a 96 well plate (col. 15, lines 42-44) (referring to claims 8-9). The method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The automated method can comprise of multiple dispensers for dispensing different reagents in a complex screening process (col. 33, lines 32-48) (referring to claim 10). Therefore, Stylli et al. anticipate the presently claimed invention.

Response to Arguments

9. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214) for claims 1-10, and 27-30 were considered but they are not persuasive for the following reasons.

Applicant contends that Stylli et al. do not anticipate the presently claimed invention because: 1) the cell-based assays disclosed in Stylli et al. help test targets, but the cells in the assay are not targets themselves. Thus the cell-based assay in Stylli et al. is not equivalent to "[*a*]*nalyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method*" as claimed in claim 1. 2) With respect to claim 2, the apparatus of Stylli et al. does not include a cartridge removably associated with a liquid injection device for containing a potential pharmaceutical active agent wherein the liquid injection device has an interior chamber defining a fixed volume for containing a potential pharmaceutical active agent. 3) With respect to claim 10, the method of Stylli et al. does not include the method step of "[*a*]*ctivating at least one second liquid ejection device in cooperation with an electrically actuated printhead to dispense a second dispense volume of a potential pharmaceutically active substance into contact with the at least one defined volume of the substance containing target cellular material*". Therefore, the method of Stylli et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the method of Stylli et al. does anticipate the presently claimed method. 1) The cell-based assay in Stylli et al. is equivalent to "[*a*]*nalyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method*" as claimed in

claim 1. Stylli et al. disclose using "whole cell" in cell based assays (col. 40, lines 20-50) and regarding Stylli et al. definition of cell based assays as being target associated with a cell refers to receptors on the cell. The assay discloses by Stylli et al. is for identifying chemicals (i.e. potential pharmaceutical active agent) that have biological activity (col. 38, lines 57-67; col. 39, lines 16-25; col. 40, lines 6-18; col. 43, lines 6-9). Thus the cell based assay in Stylli et al. is equivalent to "[*a*]*nalyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method*" as claimed in claim 1. Additionally, the passage cited by applicant (i.e. Stylli Column 43, lines 45-47) refers to the biologically active chemical (i.e. pharmaceutical active agent) is further formulated to a pharmaceutical compositions for use in vivo testing.

2) With respect to claim 2, the apparatus of Stylli et al. does include a storage and retrieval module (a removable cartridge) (col. 11, line 59 to col. 12, line 3; fig. 3, ref. #160; col. 19, lines 45-54; fig. 5, ref. #306) that is associated with a sample distribution module that can dispense large numbers of solutions (col. 12, lines 5-11). The sample distribution module comprises a liquid handler (liquid injection device) (col. 13, lines 6-15), which comprises a plurality of nanoliters dispensers (col. 15, lines 40-44). The nanoliters dispenser comprises fluid reservoir that are region of a dispenser tip that hold fluid aspirated the nanoliters dispenser (i.e. the liquid injection device has an interior chamber defining a fixed volume for containing a potential pharmaceutical active agent) (col. 16, lines 10-17). Thus the apparatus of Stylli et al. discloses the limitation of claim 2.

3) With respect to claim 10, the method of Stylli et al. does include the method step of activating a second reagent dispenser (second liquid ejection device) (col. 32, line 59 to col. 33,

line 11). The dispenser is in communication with the dispensing nozzle (printhead) (col. 16, lines 30-32, and 38-51). Thus the method of Stylli et al. discloses the limitation of claim 10.

Therefore, the method the method of Stylli et al. does anticipate the presently claimed method.

10. Claims 1, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214).

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical (pharmaceutical active agent) for modulating activity of a target (col. 38, line 46 to col. 39, line 9; col. 42, line 36 to col. 43, line 1-10). The targets of a cell-based assay are associated with a cell (col. 39, lines 7-9) (cellular material) and modulating activity such as cell proliferation (col. 4, lines 12-32). The method comprise of dispensing the reagents (therapeutic chemical) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18) (referring to claim 1). The electrically sensitive volume displacement unit can dispense a predetermined volume of 500 to 1 picoliter (col. 16, lines 39-44) (referring to claim 4 and 33). The wells are arranged in a two dimensional array such as a 96 well plate (col. 15, lines 42-44) (referring to claims 8-9, and 34). The method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The automated method can comprise of multiple dispensers for dispensing different reagents in a complex screening process (col. 33, lines 32-48), and

generating specific liquid dispensation patterns and volumes to the high-density plate (col. 60, lines3-8) (referring to claims 10, and 31-34). Therefore, Stylli et al. anticipate the presently claimed invention.

Response to Arguments

11. Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214) for claims 1, and 31-34 were considered but they are not persuasive for the following reasons.

Applicant alleges that Stylli et al. do not anticipate the presently claimed invention because the cell-based assays disclosed in Stylli et al. help test targets, but the cells in the assay are not targets themselves. Thus the cell-based assay in Stylli et al. is not equivalent to "[*a*]*nalyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method*" as claimed in claim 1.

Applicant's arguments are not convincing since the method of Stylli et al. does anticipate the presently claimed method. The cell-based assay in Stylli et al. is equivalent to "[*a*]*nalyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method*" as claimed in claim 1. Stylli et al. disclose using "whole cell" in cell based assays (col. 40, lines 20-50; col. 43, lines 6-9) and regarding Stylli et al. definition of cell based assays as being target associated with a cell refers to receptors on the cell. The assay discloses by Stylli et al. is for identifying chemicals (i.e. potential pharmaceutical active agent) that have biological activity (col. 38, lines 57-67; col. 39, lines 16-25; col. 40, lines 6-18; col. 43, lines 6-9). Thus the cell based assay in Stylli et al. is

equivalent to "[*a*]*nalyzing a pharmacologic effect on target cells and target cellular material triggered by applying a potential pharmaceutically active agent, in an automated method*" as claimed in claim 1. Additionally, the passage cited by applicant (i.e. Stylli Column 43, lines 45-47) refers to the biologically active chemical (i.e. pharmaceutical active agent) is further formulated to a pharmaceutical compositions for use in vivo testing. Therefore the method of Stylli et al. does anticipate the presently claimed method.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-10, 27-28, 31-34, and 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection.)

The instant claims 1 and 36 briefly recite an automated method for analyzing substances containing cellular material. The method comprises the steps of activating an apparatus to dispense a defined volume of a potential pharmaceutical active agent into a define volume of substance containing cellular material, detecting the pharmacological effect on the target cellular material triggered by the introduction of the defined volume of a potential pharmaceutical active agent, generating information indicative of the effect of the potential pharmaceutical active agent

on the target cellular material, and analyzing the generated information to generate a correlation factor of the relative effectiveness of the agent on the target cellular material. The apparatus comprises a cartridge that includes an interior chamber defining a fixed volume for containing the potential pharmaceutical active agent. The target cellular material is whole cells or recognized cellular components from intact cells.

The recitation of '*target cellular material*' claimed in claims 1 and 36, have no clear support in the specification and the claims as originally filed. The specification in page 9 disclosed '*typically substance or substances containing cellular material are ones which contain particular cells of interest for which evaluation of potential pharmaceutically active material is sought*' (paragraph [0035], lines 1-3) is not support for '*target cellular material*'.

The recitation of '*the relative effectiveness of the agent on the target cellular material*' claimed in claims 1 and 36, have no clear support in the specification and the claims as originally filed. The specification in page 8 disclosed '*in the case of data gathering, the result might be more quantitative, such as a factorial analysis that would tend to generate a series of equations quantifying the results*' (paragraph [0032], lines 4-6) is not support for '*the relative effectiveness of the agent on the target cellular material*'.

The recitation of '*a cartridge that includes an interior chamber defining a fixed volume for containing the potential pharmaceutical active agent*' claimed in claims 1 and 36, have no clear support in the specification and the claims as originally filed. The specification in page 12 disclosed '*preferably, the cartridge 28 has at least one reservoir containing a pharmaceutically active agent in which the reservoir containing pharmaceutically active agent is integral with a disposable printhead*' (paragraph [0044], lines 2-5) is not support for '*a cartridge that includes*

an interior chamber defining a fixed volume for containing the potential pharmaceutical active agent'.

Therefore, the scope of the invention as originally disclosed in the specification would not encompass the scope of the limitation of the presently claimed method.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-10, 27-28, 31-34, and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The limitation of "*wherein the cellular material is at least one of whole cells and recognized cellular components from intact cells*" is an improperly written Markush language. The phrase 'at least one of' is vague because it is unclear if it is referring to the 'type' of cell or cellular component or 'amount' of cells or cellular components in the target cellular material. It is suggested that for clarity the limitation be rewritten as "wherein the cellular material is whole cells and recognized cellular components from intact cells", which is a properly written Markush.

b) The phrase "relative effectiveness" of claim 1 and 36 is considered indefinite because it is unclear as to the means of measuring the degree of "relative effectiveness" (i.e. how does one measure "relative effectiveness").

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 36-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Stylli et al. (US Patent 5,985,214).

The presently claimed method recites an automated method for analyzing substances containing cellular material. The method comprises the steps of activating an apparatus to dispense a defined volume of a potential pharmaceutical active agent into a define volume of substance containing cellular material, detecting the pharmacological effect on the target cellular material triggered by the introduction of the defined volume of a potential pharmaceutical active agent, generating information indicative of the effect of the potential pharmaceutical active agent on the target cellular material, and analyzing the generated information to generate a correlation factor of the relative effectiveness of the agent on the target cellular material. The apparatus comprises a cartridge that includes an interior chamber defining a fixed volume for containing the potential pharmaceutical active agent. The target cellular material is whole cells or recognized cellular components from intact cells.

Stylli et al. disclose systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity such as biological activities, and collecting informations resulting from such a process (Abstract; col. 6, lines 1-24). The method comprise of testing a therapeutic chemical (pharmaceutical active agent) for modulating activity of a target (col. 38, line 46 to col. 39, line 9; col. 42, line 36 to col. 43, line 1-10). The assay discloses by Stylli et al. is for identifying chemicals (i.e. potential pharmaceutical active agent) that have biological activity (col. 38, lines 57-67; col. 39, lines 16-25; col. 40, lines 6-18; col. 43, lines 6-9). The assay includes cell based assay using whole cell (target cellular material) or

biological assay using target free of cells (recognized cellular components from intact cells). The method comprise of dispensing the reagents (therapeutic chemical) into the addressable sample wells, which contains a predetermined volume of the sample (cellular material) (col. 6, lines 25-40; col. 8, lines 14-18). The method includes storing, managing, and retrieving data collected from the assay process (col. 29, lines 14-26) (referring to claim 1). The automated method can comprise of multiple dispensers for dispensing different reagents in a complex screening process (col. 33, lines 32-48), and generating specific liquid dispensation patterns and volumes to the high-density plate (col. 60, lines3-8) (referring to claims 10, and 31-34). The method also includes the step of activating a second reagent dispenser (second liquid ejection device) (col. 32, line 59 to col. 33, line 11). The dispenser is in communication with the dispensing nozzle (printhead) (col. 16, lines 30-32, and 38-51). The system of Stylli et al. includes a storage and retrieval module (a removable cartridge) (col. 11, line 59 to col. 12, line 3; fig. 3, ref. #160; col. 19, lines 45-54; fig. 5, ref. #306) that is associated with a sample distribution module that can dispense large numbers of solutions (col. 12, lines 5-11). The sample distribution module comprises a liquid handler (liquid injection device) (col. 13, lines 6-15), which comprises a plurality of nanoliters dispensers (col. 15, lines 40-44). The nanoliters dispenser comprises fluid reservoir that are region of a dispenser tip that hold fluid aspirated the nanoliters dispenser (i.e. the liquid injection device has an interior chamber defining a fixed volume for containing a potential pharmaceutical active agent) (col. 16, lines 10-17). The system is integrated and programmably controlled by a computer module with a process that collects store information from each workstation (i.e. route the work unit, track work unit

inventory, and provide instruction to process samples) (col. 28, line 65 to col. 29, line 12). Therefore, Stylli et al. anticipate the presently claimed invention.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
June 10, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER